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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,344	09/10/2004	Lauretta Maggi	28069-602 NATL	3801

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EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,344	MAGGI ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 02-07-2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 02-07-2005 is acknowledged. Claims 1-27 are pending in this action. Claims 1-27 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, and 9-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/507345. Although the conflicting claims are not identical, they are not patentably distinct from each other because application '345 recites a dosage form with one or more active ingredients in a nucleus coated with polymeric material. Claim 1 of '345 reads on the first or third layer of the claim 1 in '344. The comprising language of '345 does not exclude the presence of more than one layer comprising an active ingredient, or a third layer composed of a semipermeable membrane.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "on which have been carried out by laser one or more incisions delimiting an area of geometric shape". This expression is confusing, it is unclear what applicant means by "on which have been carried out". Is the polymeric material being incised by the laser or is the incision being made on the tablet, or on the layers?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8, and 11-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayer et al. US 4810502.

Figure 2 discloses a controlled release tablet formulated with three layers. Figure 2 shows an outer layer (15) that comprises active agents pseudoephedrine and brompheniramine, a middle layer (13) made of polymers to form a semipermeable layer, and a third layer that also comprises the pharmaceutical agents listed above. The first layer (15) comprises 10-30 wt % polyethylene oxide or carboxyvinyl polymer, 30-55 wt % hydroxypropylcellulose, 2-10 wt % hydroxypropylmethylcellulose (col. 5, lines 11-15), and binders and disintegrants (col. 4, line 56 and col. 11, lines 34-36). The tablet comprises an exit means, that includes at least one passageway or orifice. The passageway can be formed by aperture, orifice, bore, pore, pourous element, hollow fiber, capillary tube (col. 8, lines 10-15). The composition of each layer is disclosed (col. 10, lines 1-68). The semipermeable membrane comprises 75% cellulose acetate and 25% hydroxypropylcellulose (col. 10, lines 18-20).

The inner and outer layers both comprise two pharmaceutically active agents. Therefore the first and third layers simultaneously comprise the same and different active ingredients and thus meet the limitations of claims 4-6. The amount of each active agent added in the top layer is different from the amount of each active agent in the inner layer (col. 11, lines 29-42).

Claim 1 is a product by process claim. (See MPEP 2112.01)

> "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical

processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)."

The product disclosed by Ayer anticipates the therapeutic system for controlled release of one or more active ingredients with previously programmed passage. Ayer is silent as to what apparatus is used to form the passageway. The process by which a product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of the prior art. In this case the prior art clearly anticipates the instant claimed product, and therefore the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not hold patentable weight. The burden is upon applicant to show that instant product is patentably distinct from Ayer's product.

Claims 1, 2, 4, 5, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte US 5487901.

Conte discloses a pharmaceutical tablet composed of an upper layer containing active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being almost completely coated with an insoluble polymeric coating (col. 2, lines 30-45). The tablets is completely coated with an impermeable polymeric film (col. 2, lines 52-53). The upper layer also comprises polymeric excipients (col. 4, lines 1-9). The amount of the excipient with respect to the total weight of the tablet is 1-90% by wt (col. 4, lines 10-13). The upper layer is 0.5-5

mm thick (col. 4, line 39). The intermediate layer is made of gelable or erodible polymers (col. 4, lines 40-53). The amount of polymeric substance in respect of the total weight of the tablet is 5-90% (col. 4, lines 55). The intermediate layer is 0.1-4.5 mm thick (col. 5, lines 31). The third layer has the same composition as the upper layer (col. 5, lines 32-36). The lower layer is 0.5-5 mm thick (col. 5, line 37). The tablet is coated with an impermeable polymeric material that is insoluble or exhibits delayed solubility, or a solubility that is pH dependent (col. 5, lines 40-46). The polymeric coating in respect of the finished tablet is 0.2-20% by wt (col. 5, lines 54-55). The upper layer is partially exposed to the environmental fluid because a raised portion was removed after final coating with impermeable polymeric coating (col. 2, lines 54-55). The reference discloses that the removal of the raised portion may be carried out by techniques already available on the market (col. 5, lines 61-64). This teaching does not rule out using laser to remove the raised portion. In any case, as was stated above in the previous rejection, claim 1 is a product by process claim. The process by which a product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of the prior art. In this case the prior art clearly anticipates the instant claimed product, and therefore the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not impart patentable weight. The burden is upon applicant to show that instant product is patentably distinct from Ayer's product.

Claims 1, 2, 4, 5, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte et al. US 5650169.

Conte '169 is a divisional of Conte '901. The disclosures are identical and the disclosure of '169 discloses all of the limitations discussed in the previous rejection. See above.

Claims 1, 3, 6-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour US 6599284 B2.

Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). The dosage form also comprises a passageway (5) formed by laser incision (col. 13, lines 48-55), which is incised in correspondence with both the first and third layer (Figure 4). The reference also teaches the addition of osmopolymers (col. 16, lines 1-45), and disintegrating agents (col. 18, lines 25-38). The reference further discloses that the outer layer or external coating layer may contain the same or different active ingredients as the inner layer (col. 13, lines 5-7). Example 1 discloses the composition of the inner core, which comprises more then 49% by wt polymeric material (col. 24, lines 15-25). Example 1 also discloses the use 5% by wt of polyethylene glycol (col. 24, lines 25-30). Faour incorporated by reference Theeuwes et al. US 4088864, which discloses the laser source as CO_2 and the output of 20W. Therefore the process claims are also anticipated by this reference.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4160020 (Ayer et al.)

US 6004582 (Faour et al.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER